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MAY 19 2020 OSM U.S. COURT OF FEDERAL CLAIMS

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS No. 19-976V (Not to be published)

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E.C.N.,	*	Chief Special Master Corcoran
on behalf of D.A.N.B, a minor,	*	•
	*	Filed: February 10, 2020
Petitioners,	*	·
v.	*	Autism; Autism Spectrum Disorder;
	*	Statute of Limitations; Evidentiary
SECRETARY OF HEALTH	*	Basis for Claim.
AND HUMAN SERVICES,	*	
	*	
Respondent.	*	
	*	
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E.C.N., San Diego, CA, pro se Petitioner.

Heather Pearlman, U.S. Dep't of Justice, Washington, D.C., for Respondent.

DECISION DISMISSING CASE¹

On July 8, 2019, E.C.N. filed a petition on behalf of her minor son, D.A.N.B., seeking compensation under the National Vaccine Injury Compensation Program ("Vaccine Program"),² Petitioner alleged that D.A.N.B. developed a toxin-induced encephalopathy manifesting as torticollis, global development delay, and autism spectrum disorder ("ASD") following a series of vaccinations he received between December 2, 2014 and January 27, 2018. Petition at 1 ("Pet.").

After several status conferences, during which I highlighted the numerous obstacles Petitioner's claim faced, I issued an order directing Petitioner to show cause why her case should

¹ This Decision will be posted on the Court of Federal Claims' website in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012). **This means that the Decision will be available to anyone with access to the internet.** As provided by 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the Decision's inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the whole Decision will be available to the public in its current form. *Id*.

² The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755 (codified as amended at 42 U.S.C. §§ 300aa-10–34 (2012)) (hereinafter "Vaccine Act" or "the Act"). All subsequent references to sections of the Vaccine Act shall be to the pertinent subparagraph of 42 U.S.C. § 300aa.

not be dismissed based on its factual similarity to other unsuccessful autism claims. *See* Scheduling Order, dated Oct. 17, 2019 (ECF No. 9). Petitioner filed a brief on January 9, 2020 in support of her claim. *See* Case Brief, filed Jan. 9, 2020 (ECF No. 16). On January 30, 2020, she filed a compact disc containing numerous pieces of literature to further bolster her allegations. Respondent filed his Response Brief on January 30, 2020. Response, filed Jan. 30, 2020 (ECF No. 18).

I. FACTUAL BACKGROUND

D.A.N.B. was born on September 18, 2014 via spontaneous vaginal delivery. Ex. 1 at 1. During his first six months of life, D.A.N.B. received several vaccinations without any reported adverse effects. Ex. 1 at 1; Ex. 2; Ex. 3 at 2–3. On April 16, 2015, one week after D.A.N.B.'s sixmonth well-baby check, Petitioner sent an email to D.A.N.B.'s pediatrician, Dr. Saemae Erfani, M.D., stating that D.A.N.B.'s head was tilting towards his left shoulder, and his left eye was pointing towards the middle of his face. Ex. 4 at 3. A week later, on April 23, 2015, Petitioner took D.A.N.B. to Dr. Erfani for a physical evaluation. Ex. 5a. During the visit, Dr. Erfani noted that D.A.N.B. had a one-week history of head tilting and intermittent eye crossing. *Id.* at 1. Dr. Erfani diagnosed D.A.N.B. with torticollis³ and congenital pseudostrabismus⁴ and referred him to an ophthalmologist as well as physical and occupational therapy.⁵ *Id.* at 2.

At D.A.N.B.'s nine-month well-baby visit on June 30, 2015, Dr. Erfani noted D.A.N.B. was healthy, and that his growth and development were within normal limits—though Dr. Erfani also noted that D.A.N.B. was not yet pulling himself up or standing. Ex. 5b at 1–2. Petitioner later took D.A.N.B. back to Dr. Erfani for his twelve-month well-baby visit. *Id.* at 6. At that time, Dr. Erfani noted that D.A.N.B. was able to walk with support, pick up small objects, say words, and play pat-a-cake. *Id.* His physical examination again revealed growth and development within normal limits. *Id.* at 7. During the visit, D.A.N.B. received the Dtap, Hepatitis A, Varicella, MMR, and Prevnar vaccines with no adverse effect reported. *Id.* at 8; Ex. 2.

One month later, on November 18, 2015, D.A.N.B. returned to Dr. Erfani for his fourteenmonth well-child visit. Ex. 8. During the visit, Petitioner reported that D.A.N.B. was experiencing car sickness. *Id.* at 1. D.A.N.B.'s physical examination was normal, and Dr. Erfani noted his growth and development as being within normal limits. *Id.* at 2. At the conclusion of the visit,

³ Torticollis is the abnormal contraction of muscles in the neck, which in turn produces a twisting of the neck and abnormal head positioning. *Dorland's Illustrated Medical Dictionary* 602 (32 ed. 2012) (hereinafter "*Dorland's*").

⁴ Congenital Pseudostrabismus is a condition that is present at birth in which the eyes' visual axes appear as though they cannot be directed at the same point of fixation. It is caused by an overhanging fold of skin near the inner corner of the eye. *Dorland's* at 403, 630, 1546, 1778.

⁵ Petitioner did not file subsequent medical records related to ophthalmology appointments, physical therapy, or occupational therapy.

D.A.N.B. received his fourth HiB vaccine in addition to a second flu vaccination. Ex. 2 at 1. No adverse reaction was noted. Dr. Erfani also ordered a lead screening.⁶ Ex. 8 at 2.

On March 29, 2016, Petitioner took D.A.N.B. for his eighteen-month well-baby visit with Dr. Erfani. Ex. 6. During the visit, Petitioner expressed concerns that D.A.N.B.'s speech was delayed, that he continued to exhibit head tilting, and that he often experienced nausea and vomiting while in the car or on the swing. *Id.* at 1. An autism screening was performed, but the results of the screening were deemed normal. *Id.* at 2. D.A.N.B. was again noted as healthy and his growth and development were within normal limits. *Id.* Dr. Erfani, however, noted that D.A.N.B.'s constellation of symptoms warranted a consultation with neurology. *Id.*

On July 26, 2016, Petitioner met with Dr. Nidia Alduncin, M.D. regarding D.A.N.B.'s symptoms. Ex. 9. During the visit, Dr. Alduncin discussed a "Multidisciplinary Diagnostic Autism Clinic" summary report. While the report itself was not filed by Petitioner, it appears that the results of the report led Dr. Alduncin to diagnose D.A.N.B. with ASD-Global Developmental Delay. *Id.* at 1. No other medical records were filed in this matter.

II. PROCEDURAL HISTORY

On July 8, 2019, E.C.N. filed a Petition, along with less than forty pages of medical records and various articles in support of her claim. An initial telephonic status conference was held with the parties on August 30, 2019. During that conference, I expressed my concerns regarding the viability of Petitioner's claim. *See* Scheduling Order, dated Sept. 3, 2019 (ECF No. 7). I explained that most of her claim was likely time-barred, given that the onset of D.A.N.B.'s symptoms appeared to *pre-date* his June 23, 2016 ASD diagnosis. *Id.* at 2. The Act's limitations period runs from the first symptoms manifestation, regardless of whether it is recognized as such, but the facts from the records in this case suggested D.A.N.B.'s onset occurred no later than March 2016—more than three years from the July 2019 filing of this Petition. Additionally, I explained to Petitioner that the claim was very unlikely to prevail on the merits in light of the vast number of autism and ASD claims that have been unsuccessfully litigated in the Program. *Id.* at 2–4.

A second telephonic status conference was held with the parties on October 16, 2019. During the status conference, I reiterated my concerns regarding the viability of the claim. I also emphasized (in response to Petitioner's objections to my comments on her claim's viability) that my role as a special master is inquisitorial, and thus any comments or opinions that I express regarding the merits of her claim are not made out of animosity or malice, but instead reflect an impartial evaluation meant to guide the parties to resolution of the claim. Despite my assurances that my evaluation of the claim was unbiased and not directed at her personally, Petitioner expressed concerns regarding her ability to pursue her claim before an impartial adjudicator and indicated that she hoped to obtain a different neutral to resolve the claim. I therefore provided a

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⁶ Petitioner did not file subsequent records documenting the results of the lead screening.

deadline by which she could file a motion for my recusal should she desire to do so. Scheduling Order, filed Oct. 17, 2019 (ECF No. 9). I also provided a briefing schedule for her to file a brief showing cause why her case should not be dismissed. *Id.* Respondent was similarly provided a deadline by which to file a response to Petitioner's brief. *Id.*

Petitioner filed a motion seeking my recusal on November 5, 2019. Motion to Disqualify, filed Nov. 5, 2019 (ECF No. 10) ("Mot. to Disqualify"). The motion also contained discovery requests seeking "all filings related to" four cases unrelated to the present matter as well as requests for the production of "[a]ll books, records, expert testimonies and documents which oppose Ms. E.C.N.'s allegation that D.A.N.B. developed toxin-induced encephalopathy manifesting as torticollis, global developmental delay, and [ASD] following a series of vaccinations." *Id.* at 5. Respondent reacted to the motion on November 13, 2019, and I issued a decision denying both discovery and my recusal on November 20, 2019. Response to Mot. to Disqualify, filed Nov. 13, 2019 (ECF No. 11); Order Denying Mot. to Disqualify, filed Nov. 20, 2019 (ECF No. 13).

On January 9, 2020, Petitioner filed her brief showing cause why her claim should not be dismissed pursuant to my October 17, 2019 Order. Shortly thereafter, Petitioner filed a compact disc containing D.A.N.B.'s vaccination record, as well as several pieces of literature to support her claim. Respondent filed his opposition to Petitioner's brief on January 30, 2020.

III. PARTIES' RESPECTIVE ARGUMENTS

A. Petitioner

In her four-page brief, Petitioner again raises the issues of recusal and discovery, and spends nearly two pages reiterating the arguments she previously made in her now-dismissed Motion to Disqualify. See Case Brief at 2–4; see also Mot. to Disqualify. On the last page of her brief, Petitioner dedicates two paragraphs to explaining why her claim should not be dismissed. Case Brief at 4. She argues that the literature she submitted "support[s] the finding that the aluminum, formaldehyde and mercury/thimerasol in the vaccines D.A.N.B. received injured him into a toxin induced encephalopathy manifesting as torticollis, global developmental delay, and [ASD]." Id. She also maintains that Respondent "has not proven" otherwise, and that Respondent has failed to produce any literature disproving that vaccines induced D.A.N.B.'s injury. Id.

B. Respondent

Respondent argues that Petitioner's claims are time-barred and are not otherwise preponderantly supported by the record, thereby warranting dismissal. Regarding the first point, Respondent cites the Vaccine Act's statutory limitations period, which requires that a petition be filed prior to "the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of [the alleged] injury." Response at 5 (citing Section 16(a)(2)). In order for me to find Petitioner's July 8, 2019 filing of the claim timely,

Respondent argues that the latest D.A.N.B. could have experienced onset of his symptoms could not have occurred before July 8, 2016. *Id.* But the onset of D.A.N.B.'s torticollis began in April 2015 (fifteen months outside of the statute of limitations), and the onset of his developmental delay and ASD also pre-date June 23, 2016 (approximately one month outside of the statute of limitations). *Id.* While Respondent does acknowledge the Vaccine Act's provision regarding equitable tolling, he argues that it is not applicable in this case *Id.* at 6–8.

Regarding the merits of the case, Respondent emphasizes that the record does not preponderantly support a causal relationship between the vaccines D.A.N.B. received and his subsequent diagnoses. *Id.* at 8–9. In support of this proposition, Respondent notes that claims alleging that vaccines can cause—or aggravate—autism or autism-like symptoms have generally not been met with success as reflected in the Omnibus Autism Proceedings ("OAP") and subsequent decisions.⁷

IV. APPLICABLE LEGAL STANDARDS

A. Petitioner's Overall Burden in Vaccine Program Cases

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that he suffered a "Table Injury"—i.e., an injury falling within the Vaccine Injury Table—corresponding to one of the vaccinations in question within a statutorily prescribed period of time

⁷ These theories were first advanced in proceedings related where thousands of petitioners' claims that certain vaccines caused autism were joined for purposes of efficient resolution. A "Petitioners' Steering Committee" was formed by many attorneys who represent Vaccine Program petitioners, with about 180 attorneys participating. This group chose "test" cases to represent the entire docket, with the understanding that the outcomes in these cases would be applied to cases with similar facts alleging similar theories.

The Petitioners' Steering Committee chose six test cases to present two different theories regarding autism causation. The first theory alleged that the measles portion of the MMR vaccine precipitated autism, or, in the alternative, that MMR plus thimerosal-containing vaccines caused autism, while the second theory alleged that the mercury contained in thimerosal-containing vaccines could affect an infant's brain, leading to autism

The first theory was rejected in three test case decisions, all of which were subsequently affirmed. See generally Cedillo v. Sec'y of Health & Human Servs., No. 98–916V, 2009 WL 331968 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), mot. for review den'd, 89 Fed.Cl. 158 (2009), aff'd, 617 F.3d 1328 (Fed. Cir. 2010); Hazlehurst v. Sec'y of Health & Human Servs., No. 03–654V, 2009 WL 332306 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), mot. for review den'd, 88 Fed.Cl. 473 (2009), aff'd, 604 F.3d 1343 (Fed. Cir. 2010); Snyder v. Sec'y of Health & Human Servs., No. 01–162V, 2009 WL 332044 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), aff'd, 88 Fed.Cl. 706 (2009).

The second theory was similarly rejected. Dwyer v. Sec'y of Health & Human Servs., No. 03–1202V, 2010 WL 892250 (Fed. Cl. Spec. Mstr. Mar. 12, 2010); King v. Sec'y of Health & Human Servs., No. 03–584V, 2010 WL 892296 (Fed. Cl. Spec. Mstr. Mar. 12, 2010); Mead v. Sec'y of Health & Human Servs., No. 03–215V, 2010 WL 892248 (Fed. Cl. Spec. Mstr. Mar. 12, 2010).

Ultimately a total of 11 lengthy decisions by special masters, the judges of the U.S. Court of Federal Claims, and the panels of the U.S. Court of Appeals for the Federal Circuit, unanimously rejected the petitioners' claims. These decisions found no persuasive evidence that the MMR vaccine or thimerosal-containing vaccines caused autism. The OAP proceedings concluded in 2010.

or, in the alternative, (2) that his illnesses were actually caused by a vaccine (a "Non-Table Injury"). See Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); see also Moberly v. Sec'y of Health & Human Servs., 592 F.3d 1315, 1321 (Fed. Cir. 2010); Capizzano v. Sec'y of Health & Human Servs., 440 F.3d 1317, 1320 (Fed. Cir. 2006). In this case, Petitioner does not assert a Table claim.

For both Table and Non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly*, 592 F.3d at 1322 n.2; *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Human Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen*: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury." *Althen*, 418 F.3d at 1278.

Each of the *Althen* prongs requires a different showing. Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355–56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id.* at 549.

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⁸ Decisions of special masters (some of which I reference in this ruling) constitute persuasive but not binding authority. *Hanlon v. Sec'y of Health & Human Servs.*, 40 Fed. Cl. 625, 630 (1998). By contrast, Federal Circuit rulings concerning legal issues are binding on special masters. *Guillory v. Sec'y of Health & Human Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff'd* 104 F. Appx. 712 (Fed. Cir. 2004); *see also Spooner v. Sec'y of Health & Human Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1378–79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325–26). Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras*, 121 Fed. Cl. at 245 ("[p]lausibility . . . in many cases *may* be enough to satisfy *Althen* prong one" (emphasis in original)).

In discussing the evidentiary standard applicable to the first Althen prong, many decisions of the Court of Federal Claims and Federal Circuit have emphasized that petitioners need only establish a causation theory's biological plausibility (and thus need not do so with preponderant proof). Tarsell v. United States, 133 Fed. Cl. 782, 792–93 (2017) (special master committed legal error by requiring petitioner to establish first *Althen* prong by preponderance; that standard applied only to second prong and petitioner's overall burden); see also Contreras, 121 Fed. Cl. at 245; Andreu, 569 F.3d at 1375. At the same time, there is contrary authority from the Federal Circuit suggesting that the same preponderance standard used overall in evaluating a claimant's success in a Vaccine Act claim is also applied specifically to the first *Althen* prong. See, e.g., Broekelschen, 618 F.3d at 1350 (affirming special master's determination that expert "had not provided a 'reliable medical or scientific explanation' sufficient to prove by a preponderance of the evidence a medical theory linking the [relevant vaccine to relevant injury].") (emphasis added). Regardless, one thing remains: petitioners always have the ultimate burden of establishing their Vaccine Act claim overall with preponderant evidence. W.C. v. Sec'y of Health & Human Servs., 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted); Tarsell, 133 Fed. Cl. at 793 (noting that Moberly "addresses the petitioner's overall burden of proving causation-in-fact under the Vaccine Act" by a preponderance standard)⁹.

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375–77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine "did cause" injury, the opinions and views of the injured party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a

⁹ Although decisions like *Contreras* suggest that the burden of proof required to satisfy the first *Althen* prong is less stringent than the other two, there is ample contrary authority for the more straightforward proposition that when considering the first prong, the same preponderance standard used overall is also applied when evaluating if a reliable and plausible causal theory has been established. *Broekelschen*, 618 F.3d at 1350.

'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Medical records and statements of a treating physician, however, do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Human Servs.*, 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing... that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted"). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should be weighed against other, contrary evidence also present in the record—including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Human Servs.*, 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Veryzer v. Sec'y of Dept. of Health & Human Servs.*, No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review denied*, 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 F. Appx. 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must align with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id.* at 1352; *Shapiro v. Sec'y of Health & Human Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. denied after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 503 F. Appx. 952 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Human Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for rev. denied* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. *Legal Governing Factual Determinations*

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider "all [] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the

record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. See Burns v. Sec'y of Health & Human Servs., 3 F.3d 415, 417 (Fed. Cir. 1993) (it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

Medical records that are created contemporaneously with the events they describe are presumed to be accurate and "complete" (i.e., presenting all relevant information on a patient's health problems). *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Human Servs.*, 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), *aff'd sub nom. Rickett v. Sec'y of Health & Human Servs.*, 468 F. Appx. 952 (Fed. Cir. 2011) (non-precedential opinion). This presumption is based on the linked propositions that (i) sick people visit medical professionals; (ii) sick people honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Human Servs.*, No. 11-685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Human Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d at 1525 (Fed. Cir. 1993) ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms").

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie*, 2005 WL 6117475, at *20. Indeed, contemporaneous medical records are generally found to be deserving of greater evidentiary weight than oral testimony—especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also Murphy*, 23 Cl. Ct. at 733 (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

There are, however, situations in which compelling oral testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Human Servs.*, 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475, at *19 ("'[w]ritten records which are, themselves, inconsistent, should be accorded less deference than

those which are internally consistent"") (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent, and compelling." Sanchez, 2013 WL 1880825, at *3 (citing Blutstein v. Sec'y of Health & Human Servs., No. 90-2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. Lalonde v. Sec'y of Health & Human Servs., 110 Fed. Cl. 184, 203-04 (2013), aff'd, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. Burns, 3 F.3d at 417.

C. Consideration of Literature

Petitioner filed several items of literature in this case, but not every filed item factored into the outcome of this decision. While I have reviewed all the literature submitted in this case, I discuss only those articles that are most relevant to my determination and/or are central to Petitioner's case. *Moriarty v. Sec'y of Health & Human Servs.*, 844 F.3d 1322, 1328 (Fed. Cir. 2016) ("[w]e generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision") (citation omitted); *see also Paterek v. Sec'y of Health & Human Servs.*, 527 F. Appx. 875, 884 (Fed. Cir. 2013) ("[f]inding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered").

D. Resolution of Case Via Ruling on Record

I have opted to resolve this matter on the papers, rather than by holding a hearing. The Vaccine Act and Rules not only contemplate but encourage special masters to decide petitions on the papers where (in the exercise of their discretion) they conclude that doing so will properly and fairly resolve the case. Section 12(d)(2)(D); Vaccine Rule 8(d). The decision to rule on the record in lieu of hearing has been affirmed on appeal. *See Kreizenbeck v. Sec'y of Health & Human Servs.*, No. 08-209V, slip op. at 8 (Fed. Cir. Jan. 6, 2020); *Hooker v. Sec'y of Health & Human Servs.*,

No. 02-472V, 2016 WL 3456435, at *21 n.19 (Fed. Cl. Spec. Mstr. May 19, 2016) (citing numerous cases where special masters decided on the papers in lieu of hearing and that decision was upheld). I am simply not required to hold a hearing in every matter, no matter the preferences of the parties. *Hovey v. Sec'y of Health & Human Servs.*, 38 Fed. Cl. 397, 402–03 (1997) (special master acted within his discretion in denying evidentiary hearing); *Burns*, 3 F.3d at 417; *Murphy* 23 Cl. Ct. at 730–31.

ANALYSIS

I. Petitioner's Claim is Untimely

As noted, the statute of limitations prescribed by the Vaccine Act is three years (thirty-six months), measured "after the expiration of 36 months after the date of the occurrence of the first symptom of manifesting of onset or of the significant aggravation of such injury." Section 16(a)(2). The statute of limitations thus begins to run from the manifestation of the first objectively cognizable symptom, whether or not that symptom is sufficient for diagnosis. *Carson v. Sec'y of Health & Human Servs.*, 727 F.3d 1365, 1369 (Fed. Cir. 2013). Special masters have appropriately dismissed cases that were filed outside the limitations period, even by a single day or two. *See, e.g., Spohn v. Sec'y of Health & Human Servs.*, No. 95-0460V, 1996 WL 532610 (Fed. Cl. Spec. Mstr. Sept. 5, 1996) (dismissing case filed one day beyond the thirty-six-month limitations period), *aff'd*, 132 F.3d 52 (Fed. Cir. 1997).

In her Petition, E.C.N. alleges that D.A.N.B.'s injury is the result of vaccinations he received between December 2, 2014 and January 27, 2018. Pet. at 1. As the record reveals, D.A.N.B. first experienced symptoms attributable to torticollis on April 16, 2015, when his mother first noticed his head tilting. Case Brief at 1; Ex. 4 at 1. She then took D.A.N.B. to Dr. Erfani on April 23, 2015, at which time Dr. Erfani noted that D.A.N.B. had been tilting his head for about one week, which is consistent with Petitioner's recollection. Ex. 5a at 1. Thereafter, D.A.N.B. exhibited symptoms of ASD and global developmental delay, including delayed speech, which was noted during an appointment with Dr. Erfani on March 29, 2016. D.A.N.B. was formally diagnosed with ASD on June 23, 2016 during a meeting with a developmental behavioral specialist, Dr. Alducin. Ex. 9 at 1.

Even taking the most liberal approach to determining the onset of D.A.N.B.'s symptoms—an approach that would put onset coinciding with D.A.N.B.'s formal ASD diagnosis on June 23, 2016 thereby requiring Petitioner's claim be filed by June 23, 2019—Petitioner's filing the claim on July 8, 2019 would still be untimely. I find, however, based upon the records filed in this case, that it is more likely that D.A.N.B.'s symptoms *pre-date* his June 2016 ASD diagnosis. Thus, I find that Petitioner's claim must be dismissed as untimely.

The Federal Circuit has held that the doctrine of equitable tolling can apply to Vaccine Act claims in limited circumstances. *See Cloer v. Sec'y of Health & Human Servs.*, 654 F.3d 1322, 1340–41 (Fed. Cir. 2011). These limited circumstances have been enumerated to include fraud and duress. *Cloer*, 654 F.3d at 1344–45 (citing *Bailey v. Glover*, 88 U.S. 342, 349-350) (1874) ("[t]o hold that by concealing a fraud, or by committing a fraud in a manner that it concealed itself until such time as the party committing the fraud could plead the statute of limitations to protect it, is to make the law which was designed to prevent fraud the means by which it is made successful and secure.")). However, the Federal Circuit has specifically stated that "equitable tolling under the Vaccine Act due to unawareness of a causal link between an injury and administration of a vaccine is unavailable" as a tolling mechanism. *Id.* at 1345.

Ultimately, none of the relevant circumstances that would permit tolling have been shown by Petitioner to apply herein. Thus, the equitable tolling doctrine does not apply, and I must therefore dismiss the present matter as untimely.

II. Petitioner's Claim Lacks Sufficient Proof

Even if Petitioner's claim had been timely filed, I find that the allegations contained therein were not sufficiently supported by reliable medical or scientific evidence to warrant compensation. Notably, less than forty pages of medical records were filed in this case, despite Petitioner having seven months to file the relevant records. The sparse record that was provided is itself devoid of any treater support for the proposition that D.A.N.B.'s torticollis, global developmental delay, and ASD were causally the result of a toxin-induced encephalopathy. The records also lack any treater support suggesting that D.A.N.B.'s condition is in any way related to the vaccinations he received.

Petitioner did offer a substantial amount of literature in support of her claim. The literature, however, is woefully deficient in establishing a causal relationship between vaccines and the alleged injuries. A large number of the articles cited by Petitioner in this case have already been reviewed by myself and other special masters in the context of autism and ASD claims, and they have time and time again been rejected due to overwhelmingly poor study designs and a general lack of support within the medical and scientific communities. *See Dwyer v. Sec'y of Health & Human Servs.*, No. 03-1202V, 2010 WL 892250, at *102–03 (Fed. Cl. Spec. Mstr. Mar. 12, 2010) (finding the strong evidence of erroneous results in A. Holmes et al., *Reduced Levels of Mercury in First Baby Haircuts of Autistic Children*, Int'l J. Toxicology 22:277–85 (2003) sufficient to discredit the study); *King v. Sec'y of Health & Human Servs.*, No. 03-584V, 2011 WL 5926126, at *21–23 (Fed. Cl. Spec. Mstr. Sept. 22, 2011) (discussing the medical and scientific community's condemning of several articles authored by David and Mark Geier and noting that an Institute of Medicine committee tasked with reviewing several studies conducted by the Geiers found them to be "so poorly done and so profoundly flawed that they effectively contributed nothing to the causation issues that they addressed.").

CONCLUSION

The untimely filing of this claim, along with a factual record devoid of any support to preponderantly establish Petitioner's contention that D.A.N.B. developed torticollis, global developmental delay, and ASD as a result of receiving his childhood vaccines, necessitate this claim's dismissal. Petitioner has not established entitlement to a damages award, and I must therefore **DISMISS** her claim.

In the absence of a timely-filed motion for review (see Appendix B to the Rules of the Court), the Clerk **SHALL ENTER JUDGMENT** in accordance with this decision.¹⁰

IT IS SO ORDERED.

s/Brian H. Corcoran Brian H. Corcoran Chief Special Master

¹⁰ Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment by filing a joint notice renouncing their right to seek review.